VEGA TECHNOLOGIES, INC.

510(K) SUMMARY

JUN 10 2011

This summary of 510(k) safety and effectiveness information is being prepared in accordance with the requirements of SMDA 1990 and 21 CFR 807.92 at June 10, 2010.

The assigned 510(k) number is: K102625

1. Submitter's Identifications:
   Establishment:
   DONGGUAN DALANG VIGOR ELECTRONICS MFY.
   Yang Wu District, Da Lang Town, Dong Guan City
   Guang Dong Prov., CHINA
   Registration Number: 9616843
   Operations: Manufacturer
   Status: Active
   Date Of Registration Status: 2004

   Owner/Operator:
   VEGA TECHNOLOGIES, INC.
   11F-13, 100 Chang-Chun Rd.,
   Taipei CHINA (Taiwan) 104.
   Owner/Operator Number: 9036509

   Contact:
   Mr. Joseph Lu
   VEGA TECHNOLOGIES, INC.
   I1F-13, 100 Chang-Chun Rd. Taipei, CHINA (TAIWAN) 104
   Phone: 886-2-2541-6996
   Fax: 886-2-2521-3803

2. Name of the Device:
   VEGA CPAP System/Heated Humidifier, model CP-03.

3. Information of the 510(k) Cleared Device (Predicate Device):
   Respironics REMstar Plus CPAP System/REMstar Heated Humidifier(K010263).

4. Device Description:

   The VEGA CPAP System/Heated Humidifier, models CP-03 is a smaller and lighter AC -powered, micro processor-controlled, and blower-based system that generates positive airway pressure from 3 to 20 cm H_2O. The device is intended for use with a patient circuit that is used to connect the device to the patient interface(mask). The CPAP device may also be used with VEGA Heated Humidifier that has been designed to be compatible with the CPAP and controlled from the CPAP. The basic functional and performance characteristics of the VEGA CPAP System/Heated Humidifier are completely similar to the predicate device, the Respironics REMstar Plus CPAP System/REMstar Heated Humidifier(K010263).

5. Intended Use:

The VEGA CPAP System/Heated Humidifier, models CP-03 delivers positive airway pressure therapy for the treatment of Obstructive Sleep Apnea only. The device is intended for use in the home or hospital/institutional environment on adult patients.

6. Comparison to the 510(k) Cleared Device (Predicate Device):

The VEGA CPAP System/Heated Humidifier, models CP-03 is substantially equivalent to the Respironics REMstar Plus CPAP System/REMstar Heated Humidifier(K010263). The main technological modification made to CP-03 as it relates to the predicate device includes the following four issues:

1> the characteristics of delivering air flow(including pressure range, and the related flow rate)
2> the operation and storage environment range.
3> the device outlook, dimensions, and weight.
4> the main power rating of air compressing motor/heating unit, control IC, and circuit, as well as software.

7. Discussion of Non-Clinical Tests Verification Activities Performed to Determine the Safety and Performance of CP-03 are as the followings:

1> Performance Compliance Test for CPAP according to ISO 17510-1 conducted by manufacturer.
2> Performance Compliance Test for heated humidifier according to ISO 17510-1 conducted by manufacturer.
3> Electrical Safety Compliance Test according to IEC 60601-1 by accredited laboratory.
4> EMC Compliance Test according to IEC 60601-1-2 by accredited laboratory.

8. Discussion of Clinical Test Validation Activities Performed to Determine the Effectiveness of Device are as the followings:

No any Clinical Test is conducted for the VEGA CPAP System/Heated Humidifier.

9. Conclusions

The VEGA CPAP System/Heated Humidifier, models CP-03, has the same intended use and technological characteristics as the cleared device of Respironics REMstar Plus CPAP System/REMstar Heated Humidifier(K010263). Moreover, verification and validation tests contained in this submission demonstrate that the difference in the submitted demonstrate that the difference in the submitted models could maintain the same safety and effectiveness as that of cleared device.

In the other words, those engineering difference do not: (1) affect the intended use or (2) alter the fundamental scientific technology of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Joseph Lu
Official Correspondent
VEGA Technologies, Incorporated
11F-13, 100 Chang-Chun Road
Taipei
CHINA (TAIWAN) 104

JUN 10 2011

Re: K102625
Trade/Device Name: VEGA CPAP System/Heated Humidifier, Models CP-03
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD, BTT
Dated: May 13, 2011
Received: May 19, 2011

Dear Mr. Lu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

VEGA TECHNOLOGIES, INC.

Indications For Use

510(k) Number (if known):_____.

Device Name: VEGA CPAP System/Heated Humidifier, models CP-03.

Indications For Use:

The VEGA CPAP System/Heated Humidifier, models CP-03 delivers positive airway pressure therapy for the treatment of Obstructive Sleep Apnea only. The device is intended for use in the home or hospital/institutional environment on adult patients.

Prescription Use __√__ OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

L Schultz

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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